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EXAMINER	
WOLLENBERGER, LOUIS V	
ART UNIT	**PAPER NUMBER**
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,693	KAEMMERER, WILLIAM F.	
	Examiner	Art Unit	
	Louis V. Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-84* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2 and 9–25, drawn to medical systems for treating a neurodegenerative disorder, wherein said neurodegenerative disorder is Parkinson's disease, classified in class 604, subclass 891.1, for example. Election of this group requires the further election of a single mRNA target, recited in claims 16–22, and a single small interfering RNA sequence, recited in claim 23, as explained below.

II. Claims 3 and 9–25, drawn to medical systems for treating a neurodegenerative disorder, wherein said neurodegenerative disorder is Alzheimer's disease, classified in class 604, subclass 891.1, for example. Election of this group requires the further election of a single mRNA target, recited in claims 16–22, and a single small interfering RNA sequence, recited in claim 23, as explained below.

III. Claims 4 and 9–25, drawn to medical systems for treating a neurodegenerative disorder, wherein said neurodegenerative disorder is Huntington's disease, classified in class 604, subclass 891.1, for example. Election of this group requires the further election of a single mRNA target, recited in claims 16–22, and a single small interfering RNA sequence, recited in claim 23, as explained below.

IV. Claims 5 and 9–25, drawn to medical systems for treating a neurodegenerative disorder, wherein said neurodegenerative disorder is spinocerebellar ataxia type 1, classified in class 604, subclass 891.1, for example. Election of this group requires the further election of a single mRNA target, recited in claims 16–22, and a single small interfering RNA sequence, recited in claim 23, as explained below.

V. Claims 6 and 9–25, drawn to medical systems for treating a neurodegenerative disorder, wherein said neurodegenerative disorder is spinocerebellar ataxia type 2, classified in class 604, subclass 891.1, for example. Election of this group requires the further election of a single mRNA target, recited in claims 16–22, and a single small interfering RNA sequence, recited in claim 23, as explained below.

VI. Claims 7 and 9–25, drawn to medical systems for treating a neurodegenerative disorder, wherein said neurodegenerative disorder is spinocerebellar ataxia type 3, classified in class 604, subclass 891.1, for example. Election of this group requires the further election of a single mRNA target, recited in claims 16–22, and a single small interfering RNA sequence, recited in claim 23, as explained below.

VII. Claims 8 and 9–25, drawn to medical systems for treating a neurodegenerative disorder, wherein said neurodegenerative disorder is dentatorubral-pallidoluysian atrophy, classified in class 604, subclass 891.1, for example. Election of this group requires the further election of a

single mRNA target, recited in claims 16–22, and a single small interfering RNA sequence, recited in claim 23, as explained below.

VIII. Claims 26, drawn to an electromechanical infusion pump, classified in class 604, subclass 19, for example.

IX. Claims 27, drawn to an osmotic infusion pump, classified in class 604, subclass 19, for example.

X. Claims 31–41 and 48–67, drawn to methods for treating neurodegenerative disorders, comprising intracranial delivery of small interfering RNA, and to methods of delivering small interfering RNA to specific locations in the brain, wherein the neurodegenerative disorder is Parkinson's disease, classified in class 514, subclass 44, for example. Election of this group requires the further election of a single mRNA target, recited in claims 53–59, as explained below.

XI. Claims 31–40, 42, and 48–67, drawn to methods for treating neurodegenerative disorders, comprising intracranial delivery of small interfering RNA, and to methods of delivering small interfering RNA to specific locations in the brain, wherein the neurodegenerative disorder is Alzheimer's disease, classified in class 514, subclass 44, for example. Election of this group requires the further election of a single mRNA target, recited in claims 53–59, as explained below.

XII. Claims 31–40, 43, and 48–67, drawn to methods for treating neurodegenerative disorders, comprising intracranial delivery of small

interfering RNA, and to methods of delivering small interfering RNA to specific locations in the brain, wherein the neurodegenerative disorder is Huntington's disease, classified in class 514, subclass 44, for example. Election of this group requires the further election of a single mRNA target, recited in claims 53–59, as explained below.

XIII. Claims 31–40, 44, and 48–67, drawn to methods for treating neurodegenerative disorders, comprising intracranial delivery of small interfering RNA, and to methods of delivering small interfering RNA to specific locations in the brain, wherein the neurodegenerative disorder is spinocerebellar ataxia type 1, classified in class 514, subclass 44, for example. Election of this group requires the further election of a single mRNA target, recited in claims 53–59, as explained below.

XIV. Claims 31–40, 45, and 48–67, drawn to methods for treating neurodegenerative disorders, comprising intracranial delivery of small interfering RNA, and to methods of delivering small interfering RNA to specific locations in the brain, wherein the neurodegenerative disorder is spinocerebellar ataxia type 2, classified in class 514, subclass 44, for example. Election of this group requires the further election of a single mRNA target, recited in claims 53–59, as explained below.

XV. Claims 31–40, 46, and 48–67, drawn to methods for treating neurodegenerative disorders, comprising intracranial delivery of small interfering RNA, and to methods of delivering small interfering RNA to

specific locations in the brain, wherein the neurodegenerative disorder is spinocerebellar ataxia type 3, classified in class 514, subclass 44, for example. Election of this group requires the further election of a single mRNA target, recited in claims 53–59, as explained below.

XVI. Claims 31–40 and 47–67, drawn to methods for treating neurodegenerative disorders, comprising intracranial delivery of small interfering RNA, and to methods of delivering small interfering RNA to specific locations in the brain, wherein the neurodegenerative disorder is dentatorubral-pallidoluysian atrophy, classified in class 514, subclass 44, for example. Election of this group requires the further election of a single mRNA target, recited in claims 53–59, as explained below.

XVII. Claims 71 and 78–84, drawn to small interfering RNAs, and to DNA sequences encoding small interfering RNAs, wherein the small interfering RNA is hybridizable to an RNA sequence encoding a protein associated with Parkinson's disease, classified in class 536, subclass 24.5, for example. Election of this group requires the further election of a single mRNA target, recited in claims 78–84, and a single small interfering RNA sequence, recited in claim 68, as explained below.

XVIII. Claims 72 and 78–84, drawn to small interfering RNAs, and to DNA sequences encoding small interfering RNAs, wherein the small interfering RNA is hybridizable to an RNA sequence encoding a protein associated with Alzheimer's disease, classified in class 536, subclass 24.5, for

example. Election of this group requires the further election of a single mRNA target, recited in claims 78–84, and a single small interfering RNA sequence, recited in claim 68, as explained below.

XIX. Claims 73 and 78–84, drawn to small interfering RNAs, and to DNA sequences encoding small interfering RNAs, wherein the small interfering RNA is hybridizable to an RNA sequence encoding a protein associated with Huntington's disease, classified in class 536, subclass 24.5, for example. Election of this group requires the further election of a single mRNA target, recited in claims 78–84, and a single small interfering RNA sequence, recited in claim 68, as explained below.

XX. Claims 74 and 78–84, drawn to small interfering RNAs, and to DNA sequences encoding small interfering RNAs, wherein the small interfering RNA is hybridizable to an RNA sequence encoding a protein associated with spinocerebellar ataxia type 1, classified in class 536, subclass 24.5, for example. Election of this group requires the further election of a single mRNA target, recited in claims 78–84, and a single small interfering RNA sequence, recited in claim 68, as explained below.

XXI. Claims 75 and 78–84, drawn to small interfering RNAs, and to DNA sequences encoding small interfering RNAs, wherein the small interfering RNA is hybridizable to an RNA sequence encoding a protein associated with spinocerebellar ataxia type 2, classified in class 536, subclass 24.5, for example. Election of this group requires the further election of a single

mRNA target, recited in claims 78–84, and a single small interfering RNA sequence, recited in claim 68, as explained below.

XXII. Claims 76 and 78–84, drawn to small interfering RNAs, and to DNA sequences encoding small interfering RNAs, wherein the small interfering RNA is hybridizable to an RNA sequence encoding a protein associated with spinocerebellar ataxia type 3, classified in class 536, subclass 24.5, for example. Election of this group requires the further election of a single mRNA target, recited in claims 78–84, and a single small interfering RNA sequence, recited in claim 68, as explained below.

XXIII. Claims 77–84, drawn to small interfering RNAs, and to DNA sequences encoding small interfering RNAs, wherein the small interfering RNA is hybridizable to an RNA sequence encoding a protein associated with dentatorubral-pallidoluysian atrophy, classified in class 536, subclass 24.5, for example. Election of this group requires the further election of a single mRNA target, recited in claims 78–84, and a single small interfering RNA sequence, recited in claim 68, as explained below.

The inventions are distinct, each from the other because of the following reasons:

Inventions I–VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Groups I–VII are drawn to products that are distinct both physically and

functionally, and are not required one for the other. While Groups I–VII are all drawn to medical systems for treating neurodegenerative disorders, each group requires a different siRNA. The device of Group I, for example, requires a deliverable amount of siRNA targeting an mRNA encoding a protein associated with Parkinson's disease, which is not required by any of the other groups. Groups II–VII, each independently require a deliverable amount of siRNA targeting an mRNA encoding a protein associated with Alzheimer's disease, Huntington's disease, spinocerebellar ataxia type 1, 2, or 3, or dentatorubral-pallidoluysian atrophy. Thus each invention performs a different function and has a different effect, targeting a different gene and treating a different disorder.

Furthermore searching Inventions I–VII together in a single application would impose a serious burden on the examiner. In the instant case, prior art searches of medical systems, including deliverable amounts of drugs or siRNAs, for treatment of Parkinson's disease are not coextensive with prior art searches of medical systems for treating Alzheimer's or Huntington's disease, spinocerebellar ataxia or dentatorubral-pallidoluysian atrophy. Searches of each of these inventions would require different key word searches of each compound and of each distinctive step of the method and of each structure in the medical device using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination.

Thus, because these inventions are distinct for the reasons given above, and because the searches are divergent and not coextensive, restriction for examination purposes as indicated is proper.

Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to physically distinct products, which have different modes of operation, and are not disclosed as capable of use together. Invention VIII is drawn to an electomechanical infusion pump, whereas Invention IX is drawn to an osmotic infusion pump. One is not required for the other and each is capable of separate manufacture and use.

Because these inventions are distinct for the reasons given above and the search required for Group VIII is not required for Group IX, restriction for examination purposes as indicated is proper.

Inventions X–XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Groups X–XVI are drawn to methods that are distinct both physically and functionally, and are not required one for the other. While Groups X–XVI are all drawn to methods for treating neurodegenerative disorders, each group requires a different siRNA. The method of Group X, for example, requires administration of siRNA targeting an mRNA encoding a protein associated with Parkinson's disease, which is

not required by any of the other groups. Groups XI–XVI, each independently require a deliverable amount of siRNA targeting an mRNA encoding a protein associated with Alzheimer's disease, Huntington's disease, spinocerebellar ataxia type 1, 2, or 3, or dentatorubral-pallidoluysian atrophy. Thus each invention performs a different function and has a different effect, targeting a different gene and treating a different disorder.

Furthermore searching Inventions X–XVI together in a single application would impose a serious burden on the examiner. In the instant case, prior art searches of methods for treating Parkinson's disease, comprising the use of siRNAs, are not coextensive with prior art searches of methods for treating Alzheimer's or Huntington's disease, spinocerebellar ataxia or dentatorubral-pallidoluysian atrophy. Searches of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination.

Thus, because these inventions are distinct for the reasons given above, and because the searches are divergent and not coextensive, restriction for examination purposes as indicated is proper.

Inventions XVII–XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Groups XVII–XXIII are drawn to small interfering RNAs, or DNA

sequences expressing small interfering RNAs, that are distinct both physically and functionally, and are not required one for the other. While Groups XVII–XXIII are all drawn to siRNAs for treating neurodegenerative diseases, each group requires a different siRNA. Group XVII, for example, is drawn to an siRNA targeting an mRNA encoding a protein associated with Parkinson's disease, which is not required by any of the other groups. Groups XVIII–XXIII, each independently require a deliverable amount of siRNA targeting an mRNA encoding a protein associated with Alzheimer's disease, Huntington's disease, spinocerebellar ataxia type 1, 2, or 3, or dentatorubral-pallidoluysian atrophy. Thus each invention performs a different function and has a different effect, targeting a different gene and treating a different disorder.

Furthermore searching Inventions XVII–XXIII together in a single application would impose a serious burden on the examiner. In the instant case, prior art searches of siRNAs for treating Parkinson's disease are not coextensive with prior art searches of siRNAs for treating Alzheimer's or Huntington's disease, spinocerebellar ataxia or dentatorubral-pallidoluysian atrophy. Searches of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination.

Thus, because these inventions are distinct for the reasons given above, and because the searches are divergent and not coextensive, restriction for examination purposes as indicated is proper.

Inventions I–VII are unrelated to VIII and IX as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the medical system is not limited to either an electromechanical or osmotic infusion pump of VIII and IX. The subcombination has separate utility such as in providing a constant level of tritiated thymidine to cultured cells.

Because these inventions are distinct for the reasons given above, and the searches required are divergent and no coextensive, and because a search of all the inventions in a single application presents a serious burden on the examiner, restriction for examination purposes as indicated is proper.

Inventions I–VII and X–XVI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the delivery of small interfering RNAs to specific locations in the brain can be accomplished by surgically implanting cells that produce small interfering RNAs specific for the disorder being treated, using standard surgical techniques and equipment, which does not require a medical system as claimed in Inventions I–VII.

Because these inventions are distinct for the reasons given above, and the searches required are divergent and no coextensive, and because a search of all the inventions in a single application presents a serious burden on the examiner, restriction for examination purposes as indicated is proper.

Inventions I–VII and XVII–XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to patentably distinct products, wherein each has a different structure and function, which require separate searches and wherein each is capable of separate manufacture and use. For example, Inventions I–VII are drawn to a medical apparatus, comprising an intracranial access device, mapping means, a deliverable amount of siRNA or vector, and delivery means. Inventions XVII–XXIII, on the other hand, are drawn to small interfering RNAs. The RNAs have properties and functions that are distinct and independent from the medical apparatus. Whereas the apparatus functions to deliver biologically active agents to defined locations in the brain, the siRNAs function to inhibit gene expression in living cells.

Because these inventions are distinct for the reasons given above, and the searches required are divergent and no coextensive, and because a search of all the inventions in a single application presents a serious burden on the examiner, restriction for examination purposes as indicated is proper.

Inventions X–XVI are related to Inventions XVII–XXIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product siRNAs of Inventions XVII–XXIII can be used as probes in Northern blotting assays to detect the presence and relative quantity of specific mRNA transcripts in cells and tissues, which does not require administering siRNAs intracranially to predetermined sites in the brain, as in Inventions X–XVI.

Because these inventions are distinct for the reasons given above, and the searches required are divergent and no coextensive, and because a search of all the inventions in a single application presents a serious burden on the examiner, restriction for examination purposes as indicated is proper.

Inventions VIII and IX are unrelated to Invention X–XVI and XVII–XXIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case VIII and IX are drawn to infusion pumps, whereas X–XVI and XVII–XXIII are drawn to methods for treating neurodegenerative disorders and to small interfering RNAs (siRNAs). The methods for treating neurodegenerative disorders do not specifically require either an electromechanical or osmotic infusion pump of VIII and IX. Similarly, the siRNAs of

XVII–XXIII can be used apart from the infusion pumps, and serve different functions and have different effects.

Because these inventions are distinct for the reasons given above, and the searches required are divergent and no coextensive, and because a search of all the inventions in a single application presents a serious burden on the examiner, restriction for examination purposes as indicated is proper.

Linked Inventions

Claim 1 links inventions I–VII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 28, 29, and 30 link Inventions X–XVI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 28,

29, and 30. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 68, 69, and 70 link Inventions XVII–XXIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 28, 29, and 30. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no

longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Election of a single siRNA sequence

Should applicant elect to prosecute any one of Groups I–VII or X–XXIII, these Groups are each subject to further restriction as follows. Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the small interfering RNA sequences recited in claims 23 and 68 (SEQ ID NOs: 1–44, and 1–4, respectively, are subject to restriction.

The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application (MPEP 803.04 and 2434).

Claim 23 specifically claims siRNAs SEQ ID Nos: 1–44, which presumably target the mRNAs recited in Claims 16–22, associated with the neurodegenerative disorders recited in Claims 2–8. Claim 68 specifically claims siRNAs SEQ ID Nos: 1–4, which presumably target the mRNAs recited in Claims 78–84, associated with the neurodegenerative disorders recited in Claims 71–77. In the instant case, the claimed siRNA sequences are considered to be unrelated, since each siRNA sequence claimed is structurally and functionally independent and distinct for the following reasons: each siRNA sequence has a unique nucleotide sequence, each siRNA sequence targets a different and specific nucleotide sequence, and absent evidence to the contrary, each

siRNA, upon binding to its target, is expected to functionally modulate (increase or decrease) the expression that target to varying degrees.

Furthermore, a search of more than one (1) of the siRNA target sequences claimed in claims 23 and 68 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed siRNA sequences. In view of the foregoing, one (1) oligonucleotide sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one siRNA sequence from Claims 23 and 68 for prosecution with the corresponding group.

As part of this election, applicant is required to elect a single mRNA target sequence from claims 16–22, 53–59, or 78–84. Each of these mRNA target sequences is considered to define a patentably distinct invention since each target is structurally and functionally distinct. Absent evidence to the contrary, the inhibition of each target requires a separate and distinct siRNA, and the regulation of each target has a separate function and gives rise to different effects. The elected mRNA target sequence must correspond to the elected siRNA sequence.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

I–VII Medical systems:

having a plurality of intracranial access devices, Claims 9 and 10;

targeting a plurality of predetermined locations in the brain, Claims 11–15; and having a plurality of delivery means, Claims 24–25.

X–XVI Methods:

targeting a plurality of predetermined sites in the brain, Claims 48–52; using a plurality of vectors, Claims 61–67.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 28, 29, 30, 69, and 70 are generic. Claims 38 and 60 are subgeneric.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on Mon–Fri, 8:00 am–4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval system (PAIR). Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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LVW July 19, 2005

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